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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/073,596	05/06/1998	RALPH M. STEINMAN	20164000US5	9977

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/073,596

Applicant(s)

Steinman et al.

Examiner

G.R. Ewoldt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 2, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82, 84-96, and 98-120 is/are pending in the application.
- 4a) Of the above, claim(s) 82, 85-88, 90, 93, 96, 98, 100, and 102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 84, 89, 91, 92, 94, 95, 99, 101, and 103-120 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Dec 2, 2002 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 84, 89, 91-92, 94-95, 97, 99, 101, and 103-120 are being acted upon.
2. The amendment and response, filed 12/02/02, is acknowledged. In view of said amendment and response, only the following rejections remain.
3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 84 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 84 remains indefinite in the recitation of "dendritic cell precursors", as the claim depends on Claim 101 which now recites "dendritic cells".
5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
6. Claims 89, 91-92, 94-95, 97, 99, 101, and 103, and newly added Claims 104-120 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (1990, IDS, of record) in view of Aldovini et al. (1991, of record), for the reasons of record as set forth in Paper No. 22, mailed 7/02/02. Note that Applicant has introduced a number of new limitations in new Claims 104-120, e.g., various sources of the dendritic cells (DCs) of the claims, however, said new limitations do not effect the patentability of the instant invention as they comprise only routine optimization and fall well within the purview of one of skill in the art at the time of the invention.

Applicant's arguments, filed 12/02/02, have been fully considered but they are not persuasive. Applicant argues that neither the references alone nor in combination teach antigen-activated DCs produced by the method of Claims 101. As the prior art teaches antigen loaded DCs, Applicant's argument appears to be that the process of the instant claims results in a patentably distinct product.

Regarding product-by-process claims, MPEP 2113 states:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985), and

"The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

It is the Examiner's position that said burden has been shifted by a showing that "the claimed product appears to be the same or similar to that of the prior art". Applicant has not attempted to show any difference between the product of the instant claims and the product of the prior art, accordingly, the rejection is proper and has been maintained.

Regarding Applicant's assertion that no motivation to combine the references has been provided, it is the Examiner's position that said motivation was set forth previously:

"It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce antigen pulsed dendritic cells that process and present antigen, as said pulsed dendritic cells could be useful for immunization

because of their natural adjuvant properties and because the dendritic cell would naturally select the antigen that could be presented on any particular MHC, as taught by Inaba et al., substituting BCG as the antigen of choice, as taught by Aldovini et al. One of ordinary skill in the art at the time the invention was made would have been motivated to make said substitution because BCG is a well-known mycobacterium antigen used in over two billion tuberculosis immunizations, as taught by Aldovini et al., to produce an improved pharmaceutical composition," i.e., the motivation of providing a superior pharmaceutical composition.

7. Claim 84 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba et al. (1990, IDS, of record) in view of Aldovini et al. (1991, of record), as applied to claims 89, 91-92, 94-95, 97, 99, 101, and 103 above, and in further view of Caux et al. (1990, IDS, of record) as evidenced by Romani et al. (1994, IDS, of record), for the reasons of record as set forth in Paper No. 22, mailed 7/02/02.

Applicant's arguments, filed 12/02/02, have been fully considered but they are not persuasive. Applicant argues that the citation of the Romani et al. reference is not proper as it was published 2 years after the earliest priority date of the instant application. It is the Examiner's position that the reference was not cited as prior art, but only as evidence of certain properties of DCs that are unrelated to priority dates. Further, the instant claims would not be granted the benefit of the 1992 priority date as the 07/981,357 application does not disclose the mycobacterial antigens of the instant claims.

8. The following are new grounds of rejection necessitated by Applicant's amendment.

9. Claim 115 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the "modified" antigen of the claim has no antecedent basis in independent Claim 101.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 99, 109, and 116 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) the recitation in Claim 99 of, "wherein the antigen-activated dendritic cells express an amount of antigen to provide between about 1 to 100 micrograms of antigen in said pharmaceutical composition."

While Applicant has now indicated where support can be found for a "modified antigen", the claim has been amended to recite the broader "antigen".

B) the recitation in Claim 109 of, "wherein the cell aggregates are subcultured about one to five times."

Applicant indicates that support for the amended claim can be found at page 28 of the specification, however no specific support for the specific limitations of the claim have been found on this page.

C) the recitation in Claim 116 of, "A pharmaceutical composition comprising a therapeutically effective amount of the composition of Claim 101."

Applicant indicates that support for the claim can be found in Claim 97, however, Claim 97 was added as an amended claim post-filing. Accordingly, said claim cannot indicate support from the specification or claims as originally filed.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

Serial No. 09/073,596
Art Unit 1644

6

statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 8:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
February 12, 2003

Pat J. Nolan

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Primary Examiner
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